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RE: Appeal Brief	APPLICATION SERIAL NUMBER: 10/773,121

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Charmaine K. Harris; Joseph J. Klein	Confirmation No.	3255
Serial No.:	10/773,121		
Filed:	February 5, 2004	Customer No.:	28863
Examiner:	Alyssa M. Alter		
Group Art Unit:	3762		
Docket No.:	1023-270US02		
Title:	PERCUTANEOUS FLAT LEAD INTRODUCER		

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via facsimile to the United States Patent and Trademark Office on November 8, 2007.

By: Shirley A. Bellach
Name: Shirley A. Bellach

Mail Stop Appeal Brief – Patents
Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

We are transmitting herewith the attached correspondence relating to this application:

☒ Appeal Brief (26 pgs.)
☒ Please charge Deposit Account No. 50-1778 in the amount of $510.00 for Appellant's Appeal Brief Fee, as required by 37 C.F.R. §41.37(a)(2).

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PATENT

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Appellant:	Charmaine K. Harris; Joseph J. Klein	Confirmation No.	3255
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APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450,
Alexandria, VA 22313

Dear Sir:

This is an Appeal Brief responsive to the Final Office Action mailed March 6, 2007. Following the Advisory Action mailed July 11, 2007, the Notice of Appeal was filed on August 10, 2007, with a one-month extension of time. Appellant also filed a Pre-Appeal Brief Request for Review with the Notice of Appeal. The Panel Decision from the Pre-Appeal Brief Review was mailed October 9, 2007. In accordance with procedures of the Pre-Appeal Brief Conference Pilot Program, the due date for this Appeal Brief is November 9, 2007.[1]

Please charge Deposit Account No. 50-1778 in the amount of $510.00 for Appellant's appeal brief fee, as required by 37 C.F.R. §41.37(a)(2).

Please charge any additional fees or credit any overpayment to Deposit Account No. 50-1778.

[1] New Pre-Appeal Brief Conference Pilot Program, 1296 Off. Gaz. Pat. Office 67 (July 12, 2005).

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REAL PARTY IN INTEREST

The real party in interest is Medtronic, Inc. of Minneapolis, Minnesota.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 1-5, 7-40 and 42-50 stand rejected under 35 U.S.C. § 103(a). Claims 1-5, 7-40 and 42-45 are also provisionally rejected for statutory double patenting under 35 U.S.C. §101. Claims 1-5, 7-40 and 42-50 are on appeal in this case.

Claims 6 and 41 are canceled. Claims 6 and 41 are not on appeal.

STATUS OF AMENDMENTS

No amendments were filed subsequent to the Final Office Action mailed March 6, 2007.

SUMMARY OF CLAIMED SUBJECT MATTER

The claims on appeal include five independent claims: claims 1, 16, 38, 46 and 49. Claim 1 is directed to a stimulation lead introducer. Claim 16 is directed to a method of introducing a stimulation lead. Claim 38 is directed to a dilator for widening a path for a stimulation lead to travel through an epidural region proximate a spine of a patient. Finally, claims 46 and 49 are each directed to a kit.[2] Claims 2-5, 7-15, 44 and 45 are dependent on claim 1; claims 17-37 are dependent on claim 16; claims 39, 40, 42 and 43 are dependent on claim 38, claims 47 and 48 are dependent on claim 46, and claim 50 is dependent on claim 49.[3] None of the claims on appeal include a means plus function or step plus function limitation as permitted by 35 U.S.C. 112, sixth paragraph.[4]

Independent claim 1 recites a stimulation lead introducer[5] comprising: an elongated dilator[6] defining a dilator lumen sized to advance over a guidewire,[7] the dilator having a

[2] *See* claims 1, 16, 38, 46 and 49.
[3] *See* claims 2-5, 7-15, 17-37, 39, 40 and 42-45, 47, 48 and 50.
[4] *See* claims 1-5, 7-40 and 42-50.
[5] *See* FIGS. 1, 5 and 6.
[6] *See* page 5, paragraph [0026] and FIG. 1.
[7] *See* page 5, paragraph [0026] and FIG. 1.

substantially conical distal tip,[8] wherein at least a portion of the conical distal tip has a substantially oblong cross-section;[9] and an elongated sheath defining a sheath lumen sized to accommodate the dilator or a stimulation lead,[10] wherein the sheath comprises a sheath material that is substantially deformable.[11]

Independent claim 16 recites a method for introducing a stimulation lead[12] comprising: inserting a stimulation lead introducer to a target site within an epidural region proximate a spine of a patient via a guidewire,[13] wherein the introducer includes: an elongated dilator[14] defining a dilator lumen sized to advance over the guidewire,[15] the dilator having a substantially conical distal tip,[16] wherein at least a portion of the conical distal tip has a substantially oblong cross-section,[17] and an elongated sheath defining a sheath lumen sized to accommodate the dilator or the stimulation lead;[18] withdrawing the dilator from the sheath;[19] and introducing a stimulation lead to the target site within the epidural region via the sheath.[20]

Independent claim 38 recites a dilator[21] for widening a path for a stimulation lead to travel through an epidural region proximate a spine of a patient,[22] the dilator having a proximal end and a distal end,[23] wherein the dilator defines a dilator lumen sized to advance over a guidewire,[24] the dilator having a substantially conical distal tip,[25] wherein at least a portion of the conical distal tip has a substantially oblong cross-section,[26] wherein the dilator lumen has a substantially oblong cross-section.[27]

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[8] *See* page 5, paragraph [0026] and FIG. 1.
[9] *See* page 5, paragraph [0027] and FIG. 1.
[10] *See* page 6, paragraph [0029] and FIG. 1.
[11] *See* page 6, paragraphs [0030]-[0031] and FIG. 1.
[12] *See* FIG. 8.
[13] *See* pages 11-12, paragraphs [0052]-[0053] and FIG. 8.
[14] *See* page 5, paragraph [0026] and FIG. 1.
[15] *See* page 5, paragraph [0026] and FIG. 1.
[16] *See* page 5, paragraph [0026] and FIG. 1.
[17] *See* page 5, paragraph [0027] and FIG. 1.
[18] *See* page 6, paragraph [0029] and FIG. 1.
[19] *See* page 12, paragraph [0053] and FIG. 8.
[20] *See* page 12, paragraph [0053] and FIG. 8.
[21] *See* FIG. 3.
[22] *See* page 7, paragraph [0035] and FIG. 3.
[23] *See* page 7, paragraph [0034] and FIG. 3.
[24] *See* page 7, paragraph [0034] and FIG. 3.
[25] *See* page 7, paragraph [0034] and FIG. 3.
[26] *See* page 7, paragraph [0035] and FIG. 3.
[27] *See* page 7, paragraph [0034] and FIG. 3.

Independent claim 46 recites a kit[28] comprising: a stimulation lead introducer, wherein the stimulation lead introducer includes: an elongated dilator[29] defining a dilator lumen sized to advance over a guidewire,[30] the dilator having a substantially conical distal tip,[31] wherein at least a portion of the conical distal tip has a substantially oblong cross-section,[32] and an elongated sheath defining a sheath lumen sized to accommodate the dilator or a stimulation lead,[33] wherein the sheath comprises a material that is substantially deformable;[34] and the stimulation lead, wherein a distal end of the stimulation lead has a substantially oblong cross-section and includes at least one electrode.[35]

Independent claim 49 recites a kit[36] comprising: a stimulation lead introducer, wherein the stimulation lead introducer includes: an elongated dilator[37] defining a dilator lumen sized to advance over a guidewire,[38] the dilator having a substantially conical distal tip,[39] wherein at least a portion of the conical distal tip has a substantially oblong cross-section,[40] and an elongated sheath defining a sheath lumen sized to accommodate the dilator or a stimulation lead; [41] and the stimulation lead, wherein a distal end of the stimulation lead has a substantially oblong cross-section and includes at least one electrode,[42] wherein a width of an outside of the sheath is within a range from approximately 5.21 millimeters to approximately 7.75 millimeters, and a height of the outside of the sheath is within a range from approximately 3.05 millimeters to approximately 3.56 millimeters,[43] and the distal end of the stimulation lead has a width within a range from approximately 3.81 millimeters to approximately 4.32 millimeters and a height within a range from approximately 1.02 millimeters to approximately 1.40 millimeters.[44]

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[28] *See* FIG. 1.
[29] *See* page 5, paragraph [0026] and FIG. 1.
[30] *See* page 5, paragraph [0026] and FIG. 1.
[31] *See* page 5, paragraph [0026] and FIG. 1.
[32] *See* page 5, paragraph [0027] and FIG. 1.
[33] *See* page 6, paragraph [0029] and FIG. 1.
[34] *See* page 6, paragraphs [0030]-[0031] and FIG. 1.
[35] *See* pages 6-7, paragraph [0032] and FIG. 1.
[36] *See* FIG. 1.
[37] *See* page 5, paragraph [0026] and FIG. 1.
[38] *See* page 5, paragraph [0026] and FIG. 1.
[39] *See* page 5, paragraph [0026] and FIG. 1.
[40] *See* page 5, paragraph [0027] and FIG. 1.
[41] *See* page 6, paragraph [0029] and FIG. 1.
[42] *See* pages 6-7, paragraph [0032] and FIG. 1.
[43] *See* pages 11-12, paragraph [0048] and FIG. 7.
[44] *See* page 11, paragraph [0048] and FIG. 7.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant submits the following grounds of rejection to be reviewed on Appeal:

(1) The first ground of rejection to be reviewed is the rejection of claims 1-5, 7-22, 24-40 and 42-50 under 35 U.S.C. § 103(a) as being unpatentable over US 2002/0147485 by Mamo et al. (Mamo) in view of US 6,146,371 to DeWindt et al. (DeWindt).

(2) The second ground of rejection to be reviewed is the rejection of claim 23 under 35 U.S.C. § 103(a) as being unpatentable over the Mamo in view DeWindt in further view of US 5,255,691 to Otten (Otten).

(3) The third ground of rejection to be reviewed is the statutory double-patenting rejection of claims 1-5, 7-40 and 42-45 under 35 U.S.C. §101 as claiming the same invention as that of claims 1-43 of copending Application Serial No. 10/718,038 (U.S. Patent Application Publication 2005/0049663).

ARGUMENT

An invention that would have been obvious to a person of ordinary skill at the time of the invention is not patentable.[45] However, the Examiner bears the burden of establishing a *prima facie* case of obviousness.[46] There are three basic requirements to establishing a *prima facie* case of obviousness.[47] First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.[48]

The Supreme Court recently clarified the standard of non-obviousness under 35 U.S.C. § 103(a) in *KSR International Co.* v. *Teleflex Inc.* (KSR).[49] In *KSR*, the Supreme Court explained the standard of obviousness by quoting *In re Kahn*,[50] " '[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' "[51] The Court further stated that the reason for modification need not conform to the particular motivation or objective of the patent Appellant.[52] An invention composed of several elements is not proved obvious merely by demonstrating that each of the elements was independently known.[53] Instead, there still must be some need or problem known in the art that would have provided a reason for combining elements in the manner claimed.[54] The Examiner must identify a logical reason why a person of ordinary skill in the art would have been led to make a modification or combination to arrive at the claimed invention.

The *KSR* case clarified that the "suggestion or motivation" requirement is more broadly a requirement that the Examiner articulate a "rational reason" for the modification. However, the *KSR* case did not modify the basic requirement of the obviousness analysis that requires the Examiner to show that the prior art collectively teaches or suggests each of the elements of

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[45] 35 U.S.C. 103(a).
[46] *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).
[47] *See* MPEP 2143.
[48] *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); *See* MPEP 2143.
[49] 550 U.S. _, 82 USPQ2d 1385 (2007).
[50] 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).
[51] *KSR*, 550 U.S. at __, 82 USPQ2d 1385, 1396.
[52] *KSR*, Slip op. at 16.
[53] *KSR*, Slip op. at 14.
[54] *KSR*, Slip op. at 16.

Appellant's claims. Accordingly, if Appellant can show that the prior art lacks a teaching of one or more elements of the pending claims, the obviousness rejections must be reversed. In addition, if Appellant can show that a person of ordinary skill in the art would not have had any *rational* reason to arrive at the claimed invention in view of the prior art, the obviousness rejections must be reversed.

Claim Rejection Under 35 U.S.C. § 103

The final Office Action mailed March 6, 2007 rejected claims 1-22 and 24-50 under 35 U.S.C. § 103(a) as being unpatentable over US 2002/0147485 by Mamo et al. (Mamo) in view of US 6,146,371 to DeWindt et al. (DeWindt). Appellant note that claims 6 and 41 are cancelled and are not on appeal. The final Office Action mailed March 6, 2007 also rejected claim 23 under 35 U.S.C. § 103(a) as being unpatentable over the Mamo in view DeWindt in further view of US 5,255,691 to Otten (Otten).

Appellant respectfully traverses the rejections, and requests reversal by the Board of Patent Appeals. It is Appellant's position that the Examiner has failed to establish a *prima facie* case of obviousness of claims 1-5, 7-40 and 42-50 under 35 U.S.C. § 103(a) in the Final Office Action dated March 6, 2007, as the applied references fail to disclose or suggest features of Appellant's claims. For this reason, Appellant respectfully submit that the rejections under 35 U.S.C. § 103(a) are improper and must be reversed.

FIRST GROUND OF REJECTION UNDER APPEAL

GROUP 1 - (Claims 1-5, 7-15, 44 and 45)

In the rejection of claim 1, the Examiner cited dilators 42 disclosed by Mamo as being equivalent to an elongated sheath, wherein the sheath comprises a sheath material that is substantially deformable. In support of this characterization, the Examiner pointed to page 4, paragraph [0074] of Mamo, which states in part, "[t]he dilators 42 can be metal or plastic . . ." The Examiner then stated, "[s]ince the dilator, which includes both the dilator body and dilator sheath, can be constructed from plastic, the sheath and dilator are both deformable."

The conclusion, that because dilators 42 can be plastic, Mamo teaches that dilators 42 may be deformable, is not logical to the extent that not all plastics are substantially deformable. For example, the plastic material of a common ballpoint pen is not substantially deformable. For this reason, further context regarding the statement that dilators 42 can be plastic is required to

logically conclude that Mamo teaches dilators 42 may comprise a material that is substantially deformable as claimed.

A proper interpretation of the term "substantially deformable" is the "broadest reasonable interpretation consistent with the specification."[55] In the Advisory Action mailed July 11, 2007, the Examiner took the position that the term "substantially deformable" includes ballpoint pens that can be flexed prior to their fracture, further stating that, even though a component may have an element of rigidity, it can still be substantially deformable. Appellant does not disagree that a component with an element of rigidity can still be substantially deformable. However, the broadest reasonable interpretation of the term substantially deformable, as applied to a sheath material as recited in claim 1, does not include sheath materials that can be flexed only to a small degree prior to their fracture, e.g., like the material of a common ballpoint pen. The Examiner's interpretation of the term "substantially deformable" is clearly unreasonable.

Appellant's specification, in view of which even a "broadest reasonable interpretation" must be made, provides evidence that the Examiner's interpretation of the term "substantially deformable" is unreasonably broad. For example, Appellant's specification provides an example sheath material that is substantially deformable as being polyethylene. Appellant's specification also provides that the "deformable properties of the material allow sheath 20 to be formed to fit the anatomy of a patient more accurately."[56] In view of Appellant's specification, the Examiner's interpretation of the term substantially deformable as it relates to the recited sheath material is unreasonably broad.

At least because the Examiner has failed to provide any suggestion or evidence that plastic used to form dilators 42 as disclosed by Mamo is substantially deformable within the broadest reasonable interpretation consistent with Appellant's specification, the Examiner has failed to meet the burden of providing a prima facie case of obviousness with respect to claim 1. Furthermore, the disclosure of Mamo provides context that suggests the opposite is true, i.e., that the plastic used to form dilators 42 would be substantially rigid, not substantially deformable.

For example, as shown in FIG. 9d and described in paragraph [0100] of Mamo, "guide wire 44 is stiff and straight and is long enough so that the dilator 42' can be inserted over the guide wire 44 outside of the patient's skin." FIG. 9d illustrates that dilator 42' is perfectly straight. From this context, one of skill in the art would understand that dilator 42' should be

[55] *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005).
[56] Application, page 6, paragraph [0030] and FIG. 1.

made of a material that is stiff, not substantially deformable as claimed. As another example of how the context of Mamo demonstrates that plastic used to form dilators 42 would be substantially rigid, a dilator that is substantially deformable would not function in the same manner as one that is stiff. However, when the possibility of a plastic dilator is mentioned in paragraph [0074], Mamo fails to note any functional difference between a dilator that is metal, which is presumably stiff, and a dilator that plastic. In this manner, Mamo clearly fails to teach or suggest the feature of an elongated sheath, wherein the sheath comprises a sheath material that is substantially deformable as claimed.

DeWindt also fails to teach or suggest the feature of an elongated sheath, wherein the sheath comprises a sheath material that is substantially deformable. For at least these reasons, the cited references fail to disclose or suggest each of the features recited by Appellant's claim 1, and the obviousness rejection of claim 1 under 35 U.S.C. § 103(a) should be withdrawn.

The applied references also fail to disclose or suggest a stimulation lead introducer comprising an elongated dilator, wherein at least a portion of the conical distal tip of the dilator has a substantially oblong cross-section, as recited in independent claim 1. In the rejection of claim 1, the Examiner acknowledged that Mamo fails to disclose an elongated dilator with an oblong cross-section, but stated that DeWindt would have made it obvious to modify a dilator of Mamo to have an oblong cross-section.

To establish prima facie case of obviousness, the Office Action is required to demonstrate that the applied references teach or suggest all the claim limitations.[57] However, neither Mamo nor DeWindt suggests an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. The Office Action admitted that Mamo fails to disclose such a feature. Furthermore, DeWindt fails to even *discuss* a dilator.

Instead, DeWindt discloses a cannula for use in conducting fluid to or from a body.[58] The DeWindt cannula is not an elongated dilator. Accordingly, neither Mamo nor DeWindt discloses or suggests an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section, as required by independent claim 1.

Furthermore, the teachings of DeWindt would not have suggested modification of the shape of the Mamo dilator to a person of ordinary skill in the art at the time of Applicant's invention. The Examiner stated that the reason a person of ordinary skill in the art would have

[57] *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).
[58] *See*, e.g., DeWindt et al., column 1, lines 41-42.

sought to modify the dilator of Mamo with the oblong or oval shape of DeWindt would have been to utilize available space more efficiently. DeWindt teaches use of an oval-shape in a cannula to provide an equivalent flow rate to that of a round cannula, while not extending as far toward the center of an access aperture, which is helpful to provide space outside of the cannula for other uses of the access aperture.[59]

This teaching would not have suggested any modification of the Mamo dilator. Use of the Mamo dilator does not involve considerations of flow rate. Moreover, use of the Mamo dilator does not require any space outside of the dilator but within an access aperture.[60] Accordingly, a person of ordinary skill would have seen no reason to modify the Mamo dilator based on the DeWindt teachings.

It appears that the Examiner found DeWindt to be relevant because it discloses an oval shape. However, a person of ordinary skill would not have considered any feature of the cannula disclosed in DeWindt to be relevant to a dilator as disclosed in Mamo. *KSR* did not eliminate the need for the Examiner to support conclusory statements with underlying facts.[61] The Examiner provided no rationale or evidence as to why a person of ordinary skill would have turned to the DeWindt cannula for modification of the Mamo introducer. Accordingly, it appears that the Examiner impermissibly used Appellant's disclosure as a blueprint to combine attributes of two unrelated devices and thereby reproduce the Appellant's invention.

The applied references fail to disclose or suggest an elongated sheath, wherein the sheath comprises a sheath material that is substantially deformable and also fail to disclose or suggest an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. For at least these reasons, the Office Action has failed to provide a prima facie case of obviousness for claim 1 as required to support a rejection under 35 U.S.C. §103(a). Appellant respectfully requests reversal of the rejection of claim 1 and dependent claims 2-5, 7-15, 44 and 45.

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[59] DeWindt et al., column 3, line 66 – column 4, line 5.

[60] *See*, Mamo et al. FIG. 6i and paragraph [0085].

[61] "The board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies." *In re Lee*, 277 F.3d 1338, 1344-45, 61 USPQ2d 1430, 1434-35 (Fed. Cir. 2002).

GROUP 2 - (Claims 16-22 and 24-37)

As discussed with respect to independent claim 1, the applied references fail to disclose or suggest an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. Specifically, neither Mamo nor DeWindt discloses such a feature, and the teachings of DeWindt would not have suggested modification of the Mamo dilator to incorporate such a feature.

Claim 16 also contains additional elements not addressed by the Examiner, which are not taught or suggested by either Mamo or DeWindt. For example, Mamo and DeWindt fail to disclose or suggest inserting a stimulation lead introducer into an epidural region proximate a spine of a patient via a guidewire. In contrast, Mamo discloses implantation of a sacral stimulation lead through a foramen of the sacrum in a patient.[62]

For at least these reasons, the Examiner has failed to establish a prima facie case of obviousness for claim 16 as required to support a rejection under 35 U.S.C. §103(a). Appellant respectfully requests reversal of the rejection of independent claim 16 and dependent claims 17-19, 21 22 and 24-37.

GROUP 3 - (Claim 20)

Claim 20 is patentable for at least the reasons independent claim 16 is patentable. In addition claim 20 recites additional features not found in or suggest by the cited prior art. For example, the applied references completely fail to disclose or suggest attaching a syringe to the needle, prior to inserting the guidewire into the needle, and attempting to inject fluid into the epidural region via the syringe and the needle to evaluate a position of the needle, as recited by claim 20.

The Examiner failed to account for this feature, and Appellant finds no teaching or suggestion of such a feature in the cited references.

For at least these reasons, the Examiner has failed to establish a prima facie case of obviousness for claim 20 as required to support a rejection under 35 U.S.C. §103(a). Appellant respectfully requests reversal of the rejection of claim 20.

[62] Mamo et al., abstract.

GROUP 4 - (Claims 38-40, 42 and 43)

As discussed with respect to independent claim 1, the applied references fail to disclose or suggest a dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. Specifically, neither Mamo nor DeWindt discloses such a feature, and the teachings of DeWindt would not have suggested modification of the Mamo dilator to include such a feature.

Claim 38 also contains additional elements not addressed by the Examiner, which are not taught or suggested by either Mamo or DeWindt. For example, Mamo and DeWindt fail to disclose or suggest a dilator for widening a path for a stimulation lead to travel through an epidural region proximate a spine of a patient. In contrast, Mamo discloses a dilator for implantation of a sacral stimulation lead through a foramen of the sacrum in a patient.[63]

For at least these reasons, the Examiner has failed to establish a prima facie case of obviousness for claim 38 as required to support a rejection under 35 U.S.C. §103(a). Appellant respectfully requests reversal of the rejection of claim 38 and dependent claims 39-45.

GROUP 5 - (Claims 46-48)

As discussed with respect to independent claim 1, the applied references fail to disclose or suggest an elongated sheath, wherein the sheath comprises a material that is substantially deformable. The applied references fail to disclose or suggest an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. Specifically, neither Mamo nor DeWindt discloses such features, and the teachings of DeWindt would not have suggested modification of the Mamo dilator sheath to include such a features.

Claim 46 contains additional elements not addressed by the Examiner, which are not taught or suggested by either Mamo or DeWindt. For example, Mamo and DeWindt fail to disclose or suggest a kit including a stimulation lead, wherein a distal end of the stimulation lead has a substantially oblong cross-section and includes at least one electrode. In contrast, Mamo discloses a stimulation lead having a round cross-section.[64]

For at least these reasons, the Examiner has failed to establish a prima facie case of obviousness for claim 46 as required to support a rejection under 35 U.S.C. §103(a). Appellant respectfully requests reversal of the rejection of claim 46 and dependent claims 47 and 48.

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[63] Mamo et al., abstract.
[64] *See*, e.g., Mamo et al., FIGS. 5i-5k.

GROUP 6 - (Claim 49)

As discussed with respect to independent claim 1, the applied references fail to disclose or suggest an elongated sheath, wherein the sheath comprises a material that is substantially deformable, as required by independent claim 49. Furthermore, as also discussed above, the applied references fail to disclose or suggest an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section, as required by claim 49. As discussed above with reference to claim 1, neither Mamo nor DeWindt discloses such features, and the teachings of DeWindt would not have suggested modification of the Mamo dilator sheath to include such features.

Claim 49 contains additional elements not addressed by the Examiner, which are not taught or suggested by either Mamo or DeWindt. For example, Mamo and DeWindt fail to disclose or suggest a kit including a stimulation lead, wherein a distal end of the stimulation lead has a substantially oblong cross-section and includes at least one electrode. In contrast, Mamo discloses a stimulation lead having a generally round cross-section.[65]

For at least these reasons, the Office Action has failed to provide a prima facie case of obviousness for claim 49 as required to support a rejection under 35 U.S.C. §103(a). Appellant respectfully requests reversal of the rejection of claim 46 and dependent claim 50.

GROUP 7 - (Claim 50)

Claim 50 is patentable for at least the reasons independent claim 49 is patentable. In addition claim 50 recites additional features not found in or suggest by the cited prior art. For example, the applied references completely fail to disclose or suggest a dilator and sheath that are sized to enter an epidural region of a patient, as recited by claim 50.

The Office Action fails to cite any explicit support for the rejection of claim 50, instead stating that the recited elements simply consist of the optimum or workable ranges. However, the cited references fail to even consider implantation in the epidural region of a patient. Instead, the disclosure of Mamo is related to implanting a stimulation lead in a patient's sacrum.[66] Absent some suggestion or reason to use the Mamo apparatus in the epidural region, a person of ordinary skill in the art at the time of Applicant's invention would not have sought to size the Mamo for

[65] *See*, e.g., Mamo et al., FIGS. 5i-5k.
[66] *See*, e.g., Mamo et al., abstract.

entry into the epidural region. Consequently, the feature of a dilator and a sheath that are sized to enter an epidural region of a patient would clearly not have been obvious to one of ordinary skill in the art in view of the cited references.

For at least these reasons, the Examiner has failed to establish a prima facie case of obviousness for claim 50 as required to support a rejection under 35 U.S.C. § 103(a). Appellant respectfully requests reversal of the rejection of claim 50.

SECOND GROUND OF REJECTION UNDER APPEAL

GROUP 8 - (Claim 23)

Claim 23 is dependent on independent claim 16. Otten fails to overcome the deficiencies of Mamo in view of DeWindt as discussed with respect to independent claim 16. For example, Otten fails to teach or suggest an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section.

For at least these reasons, the Examiner has failed to establish a prima facie case of obviousness for claim 23 as required to support a rejection under 35 U.S.C. §103(a). Appellant respectfully requests reversal of the rejection of claim 23.

THIRD GROUND OF REJECTION UNDER APPEAL

Claims 1-5, 7-40 and 42-45

The Office Action provisionally rejected claims 1-5, 7-40 and 42-45 under 35 U.S.C. §101 as claiming the same invention as that of claims 1-43 of copending Application Serial No. 10/718,038 (U.S. Patent Application Publication 2005/0049663). Application Serial No. 10/718,038 is presently abandoned. In other words, there is no basis for the provisional double patenting rejection because the conflicting claims of Application Serial No. 10/718,038 will never be patented. Accordingly, Applicant respectfully requests that this provisional rejection be reversed.

CONCLUSION OF ARGUMENT

The Examiner has failed to meet the burden of establishing a prima facie case of obviousness with respect to claims 1-5, 7-40 and 42-50. In view of Appellant's arguments, the final rejection of claims 1-5, 7-40 and 42-50 is improper and should be reversed, and all of the pending claims should be allowed. Appellant respectfully requests separate review by the Board for each of the grounds or rejection addressed above under separate headings.

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CLAIMS APPENDIX

1. A stimulation lead introducer comprising:

an elongated dilator defining a dilator lumen sized to advance over a guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section; and

an elongated sheath defining a sheath lumen sized to accommodate the dilator or a stimulation lead, wherein the sheath comprises a sheath material that is substantially deformable.

2. The stimulation lead introducer of claim 1, wherein the sheath has a substantially oblong cross-section.

3. The stimulation lead introducer of claim 1, wherein the sheath has a substantially oblong cross-section with a width of the cross-section of the sheath that is greater than approximately two times a height of the cross-section of the sheath.

4. The stimulation lead introducer of claim 1, wherein the dilator lumen has a substantially oblong cross-section.

5. The stimulation lead introducer of claim 1, wherein the sheath lumen has a substantially oblong cross-section.

7. The stimulation lead introducer of claim 1, wherein the sheath material is polyethylene.

8. The stimulation lead introducer of claim 1, wherein the dilator comprises a dilator material that is substantially deformable.

9. The stimulation lead introducer of claim 8, wherein the dilator material is polyethylene.

10. The stimulation lead introducer of claim 1, wherein the dilator is at least as long as the sheath.

11. The stimulation lead introducer of claim 1, wherein the substantially conical distal tip comprises a proximal opening and a distal opening, the proximal opening having a substantially oblong cross-section and the distal opening having a substantially circular cross-section.

12. The stimulation lead introducer of claim 1, wherein the substantially conical distal tip comprises a proximal opening having an oblong cross-section such that a width of the proximal opening is greater than a height of the proximal opening.

13. The stimulation lead introducer of claim 12, wherein the width of the proximal opening is greater than or equal to approximately three times the height of the proximal opening.

14. The stimulation lead introducer of claim 1, wherein the sheath includes radiopaque material that is viewable under fluoroscopic imaging.

15. The stimulation lead introducer of claim 1, wherein the sheath lumen has a cross-section with a width of the cross-section of the sheath lumen that is greater than approximately two times a height of the cross-section of the sheath lumen.

16. A method for introducing a stimulation lead comprising:

inserting a stimulation lead introducer to a target site within an epidural region proximate a spine of a patient via a guidewire, wherein the introducer includes:

an elongated dilator defining a dilator lumen sized to advance over the guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section, and

an elongated sheath defining a sheath lumen sized to accommodate the dilator or the stimulation lead;

withdrawing the dilator from the sheath; and

introducing a stimulation lead to the target site within the epidural region via the sheath.

17. The method of claim 16, further comprising:

inserting a needle with a stylet into the epidural region proximate a spine of a patient;

withdrawing the stylet from the needle;

inserting the guidewire into the needle such that a distal end of the guidewire extends to the target site within the epidural region;

withdrawing the needle;

inserting the stimulation lead introducer into the patient via the guidewire following withdrawal of the needle;

withdrawing the guidewire; and

introducing the stimulation lead via the sheath following withdrawal of the dilator and the guidewire.

18. The method of claim 17, further comprising withdrawing the sheath.

19. The method of claim 17, further comprising activating the stimulation lead to stimulate a nerve.

20. The method of claim 17, further comprising attaching a syringe to the needle, prior to inserting the guidewire into the needle, and attempting to inject fluid into the epidural region via the syringe and the needle to evaluate a position of the needle.

21. The method of claim 17, further comprising using an imaging technique to visualize introduction of the stimulation lead.

22. The method of claim 21, wherein the imaging technique comprises fluoroscopic imaging.

23. The method of claim 17, wherein the needle is a Tuohy needle.

24. The method of claim 16, wherein the sheath has a substantially oblong cross-section.

25. The method of claim 16, wherein the sheath has a substantially oblong cross-section with a width of the cross-section of the sheath that is greater than approximately two times a height of the cross-section of the sheath.

26. The method of claim 16, wherein the dilator lumen has a substantially oblong cross-section.

27. The method of claim 16, wherein the sheath lumen has a substantially oblong cross-section.

28. The method of claim 16, wherein the sheath comprises a material that is substantially deformable.

29. The method of claim 28, wherein the material is polyethylene.

30. The method of claim 16, wherein the dilator comprises a material that is substantially deformable.

31. The method of claim 30, wherein the material is polyethylene.

32. The method of claim 16, wherein the dilator is at least as long as the sheath.

33. The method of claim 16, wherein the substantially conical distal tip comprises a proximal opening and a distal opening, the proximal opening having a substantially oblong cross-section and the distal opening having a substantially circular cross-section.

34. The method of claim 16, wherein the substantially conical distal tip comprises a proximal opening having an oblong cross-section such that a width of the proximal opening is greater than a height of the proximal opening.

35. The method of claim 34, wherein the width of the proximal opening is greater than or equal to approximately three times the height of the proximal opening.

36. The method of claim 16, wherein the sheath includes radiopaque material that is viewable under fluoroscopic imaging.

37. The method of claim 16, wherein the sheath lumen has a cross-section with a width of the cross-section of the sheath lumen that is greater than approximately two times a height of the cross-section of the sheath lumen.

38. A dilator for widening a path for a stimulation lead to travel through an epidural region proximate a spine of a patient, the dilator having a proximal end and a distal end, wherein the dilator defines a dilator lumen sized to advance over a guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section,

wherein the dilator lumen has a substantially oblong cross-section.

39. The dilator of claim 38, wherein the dilator is formed from a material that is substantially deformable.

40. The dilator of claim 39, wherein the material is polyethylene.

42. The dilator of claim 38, wherein the substantially conical distal tip comprises a proximal opening and a distal opening, the proximal opening having a substantially oblong cross-section and the distal opening having a substantially circular cross-section.

43. The dilator of claim 38, wherein the width of the proximal opening is greater than or equal to approximately three times the height of the proximal opening.

44. The stimulation lead introducer of claim 1, wherein a width of an outside of the sheath is within a range from approximately 5.21 millimeters to approximately 7.75 millimeters, and a height of the outside of the sheath is within a range from approximately 3.05 millimeters to approximately 3.56 millimeters.

45. The stimulation lead introducer of claim 1, wherein the dilator and the sheath are sized for insertion into an epidural region of a patient.

46. A kit comprising:

a stimulation lead introducer, wherein the stimulation lead introducer includes:

an elongated dilator defining a dilator lumen sized to advance over a guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section, and

an elongated sheath defining a sheath lumen sized to accommodate the dilator or a stimulation lead, wherein the sheath comprises a material that is substantially deformable; and

the stimulation lead, wherein a distal end of the stimulation lead has a substantially oblong cross-section and includes at least one electrode.

47. The kit of claim 46, wherein the distal end of the stimulation lead has a substantially rectangular cross-section.

48. The kit of claim 46, wherein the distal end of the stimulation lead is substantially paddle-shaped.

49. A kit comprising:

a stimulation lead introducer, wherein the stimulation lead introducer includes:

an elongated dilator defining a dilator lumen sized to advance over a guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section, and

an elongated sheath defining a sheath lumen sized to accommodate the dilator or a stimulation lead; and

the stimulation lead, wherein a distal end of the stimulation lead has a substantially oblong cross-section and includes at least one electrode,

wherein a width of an outside of the sheath is within a range from approximately 5.21 millimeters to approximately 7.75 millimeters, and a height of the outside of the sheath is within a range from approximately 3.05 millimeters to approximately 3.56 millimeters, and the distal end of the stimulation lead has a width within a range from approximately 3.81 millimeters to approximately 4.32 millimeters and a height within a range from approximately 1.02 millimeters to approximately 1.40 millimeters.

50. The kit of claim 49, wherein the dilator and the sheath are sized to enter an epidural region of a patient.

EVIDENCE APPENDIX

NONE

RELATED PROCEEDINGS APPENDIX

NONE